K062795

510(K) SUMMARY

DEC 1 1 2006

5.1 Submitter Information

A.	Company Name:	Access Pharmaceuticals, Inc.
B.	Company Address:	2600 Stemmons Freeway, Suite 176 Dallas, TX 75207
C.	Company Phone:	(214) 905-5100
D.	Company Facsimile:	(214) 905-5101
E.	Contact Person:	David P. Nowotnik Senior Vice-President, Research & Development david.nowotnik@accesspharma.com

5.2 Device Identification

A.	Device Trade Name:	MuGard™ Mucoadhesive Oral Wound Rinse
B.	Common Name:	Dressing, Wound and Burn, Hydrogel w/ Drug and/or Biologic
C.	Classification Name:	Unclassified
D.	Device Class:	Unclassified
E.	Device Code:	MGQ
E.	Advisory Panel:	General and Plastic Surgery

5.3 Identification of Predicate Devices

The MuGard™ Mucoadhesive Oral Wound Rinse is substantially equivalent to the following predicate devices:

- OraMagicRx™ Oral Wound Rinse manufactured by MPM Medical, Inc. and cleared for commercial distribution under 510(k) K024180.
- Gelclair® Concentrated Oral Gel manufactured by Sinclair Pharmaceuticals, Ltd. and cleared for commercial distribution under 510(k) K013056.

5.4 Device Description

MuGard™ Mucoadhesive Oral Wound Rinse is a viscous liquid supplied in plastic bottles and is designed for the management of oral mucositis/stomatitis and other oral wounds. When swirled gently round the mouth, the mucoadhesive formulation results in the formation of a protective coating over the oral mucosa.

5.5 Indications for Use

MuGard™ Mucoadhesive Oral Wound Rinse is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

5.6 Comparison to Predicate Devices

MuGard™ Mucoadhesive Oral Wound Rinse is similar in function and has the same intended use as OraMagicRx™ Oral Wound Rinse (MPM Medical, Inc.), Gelclair® Concentrated Oral Gel (Sinclair Pharmaceuticals, Ltd.) and other legally marketed hydrogel wound dressing products.

The mode of action of MuGard™ Mucoadhesive Oral Wound Rinse is achieved in an same manner to OraMagicRx™ Oral Wound Rinse and Gelclair® Concentrated Oral Gel, i.e., through the formation of a protective layer over the oral mucosa.

The composition of MuGard™ Mucoadhesive Oral Wound Rinse is similar to OraMagicRx™ Oral Wound Rinse and Gelclair® Concentrated Oral Gel, i.e., a mixture of film-forming polymers, pharmaceutical aids, preservatives and sweeteners/flavors.

The safety of MuGard™ Mucoadhesive Oral Wound Rinse has been established through biocompatibility testing according to ISO 10993, i.e., *in vitro* cytotoxicity tests, sensitization testing in guinea pigs and mucosal irritation testing in rabbits.

On the basis of this information, Access Pharmaceuticals concluded that MuGard™ Mucoadhesive Oral Wound Rinse is safe and effective for its intended use and performs equivalently to the identified legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2006

Dr. David P. Nowotnik
Senior Vice President, Research & Development
Access Pharmaceuticals, Incorporated
2600 Stemmons Freeway, Suite 176
Dallas, Texas 75207

Re: K062795
Trade/Device Name: MuGard™ Mucoadhesive Oral Wound Rinse
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MGQ
Dated: September 15, 2006
Received: September 18, 2006

Dear Dr. Nowotnik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

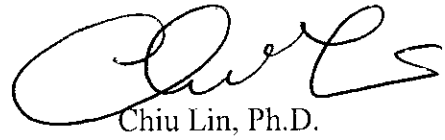
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: MuGard™ Mucoadhesive Oral Wound Rinse

Indications for Use:

MuGard™ Mucoadhesive Oral Wound Rinse is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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